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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,183	03/30/2001	Paul C. Reardon	01801-P0026A	9166

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EXAMINER

NGUYEN, BAO THUY L 12

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/823,183

Applicant(s)

REARDON, PAUL C.

Examiner

Bao-Thuy L. Nguyen

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: All of record.Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See attached.

Bao-Thuy L. Nguyen
Primary Examiner
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ADVISORY ACTION

1. Applicant's after final arguments filed March 10, 2003 have been fully considered but they are not persuasive.

Applicant argues that claims 1 and 13 require a conjugate pad, which is not disclosed, taught or suggested by May or Massaro. Applicant argues that claims 1 and 13 requires two separate components, i.e. a conjugate pad and a chromatographic test strip. Applicant also points to figure 1 of May to support the argument that May does not teach two separate components.

These arguments have been fully considered but is not deemed to be persuasive. May discloses several embodiment of the device. One specific embodiment (embodiment 3, figures 8 and 9 and pages 22-26) teaches a device comprising a porous member 506 overlapping a carrier test strip 510. The porous member 506 is adapted for receiving a sample fluid and can contain a labeled reagent. See page 26, lines 4-5. This porous member is the same with the conjugate pad of the instant claims. Even though the porous member 506 is not designated as a conjugate pad, it is seen to be the same with the instant conjugate pad because they both serve the same function and carry the same reagent. Nothing in the instant conjugate pad distinguishes it from the labeled reagent zone taught by May.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the instant method and device is highly sensitive and capable of reliably detecting Bence Jones proteins in low concentration in untreated urine) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057

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(Fed. Cir. 1993). Because the instant device and method are seen to be obvious in view of the teachings of May and Massaro and because May teaches that a solid phase device provides specific advantages, and can be modified to determine the presence of a very wide variety of analytes if appropriate reagents were incorporated in the test strip (page 25, lines 25-30), the combination of May and Massaro is proper and is maintained.

Applicant argues that Brizgy does not fill the deficiencies noted in May and Massaro, namely a conjugate pad and an assay using untreated urine to obtain highly sensitive and reliable results.

These arguments have been fully considered but are not deemed to be persuasive. May teaches the conjugate pad as stated above. May also teaches the use of untreated urine and Massaro teaches the advantages of detecting Bence Jones proteins (i.e. free light chains and classes thereof, column 1, lines 6-34) as stated in the previous office actions, paper nos. 5 and 10. Brizgy is noted for its teaching Protein A as a capture reagent. A highly sensitive and reliable assay result is not a limitation of the claims and thus this argument is not on point.

Applicant argues that the addition of Deutsch does not fill the deficiencies noted against May and Massaro or Brizgy because Deutsch does not suggest the advantages of using untreated urine to obtain highly sensitive results.

This argument has been fully considered but is not deemed to be persuasive. The use of untreated urine is taught by May above. Deutsch is noted for its teaching of a test tube for holding a liquid sample. The argument of a sensitive assay results is not claimed and thus is not on point.

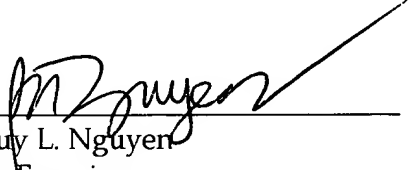
2. No claim is allowed.

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
March 21, 2003